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Attitudes of Cystic Fibrosis Patients and Their Parents Towards Direct-to-Consumer Genetic Testing for Carrier Status

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Abstract and Introduction

Abstract

Background An increasing number of direct-to-consumer (DTC) genetic testing companies have started offering tests for carrier status of autosomal recessive disorders.

Materials & Methods A written questionnaire was administered to 47 patients and 65 parents of children with Cystic Fibrosis (CF), a common severe autosomal recessive disorder, to assess their views about the offer of DTC carrier tests. All participants were recruited from a CF patient registry in Belgium.

Results & Conclusion We found that very few patients and parents were aware of the offer of DTC genetic testing for carrier status, and were generally skeptical. A strong preference for the healthcare system over commercial companies as the provider of the test was observed. However, many participants believe people should have a right to access DTC genetic tests provided by commercial companies.

Introduction

Cystic fibrosis (CF) is a common severe autosomal recessive disorder mostly affecting people of Northern European ancestry. The prevalence of CF is estimated at 1 per 2500–4000 live births and the carrier frequency is approximately 1 in 25 to 1 in 30.[1] If both parents are carriers, there is a 1-in-4 chance that each child of the couple will be affected by CF. The gene responsible for the disease was identified in 1989,[2] which made carrier testing for CF possible. While carrier testing can be performed at any stage in life, it has been suggested that the procedure offers most benefits to couples considering a pregnancy (preconception screening).[3] Informing prospective parents about their likelihood of having a child with CF allows these couples to make informed reproductive decisions.[4] The options available to couples identified as carriers include selection of healthy embryos using preimplantation genetic diagnosis, or prenatal diagnosis with the potential for termination of pregnancy. Alternatively, carrier couples may instead choose to accept the risk and conceive naturally, avoid pregnancy altogether, use egg or sperm donation, or adopt a child.

Even though population-based carrier screening for CF has been discussed since the early 1990s, as of 2013, very few countries offered fee-for-service carrier screening for CF to the population.[5] Despite the absence of CF screening programs in many countries, individuals without a family history for the condition seeking carrier screening for CF can order the test also outside the traditional healthcare setting, through direct-to-consumer (DTC) genetic testing companies. DTC genetic testing companies market and sell, among other services, genetic tests for various monogenic and complex disorders directly to consumers. The service is usually provided through the Internet and without the involvement of a licensed healthcare provider.[6] The UK Human Genetics Commission extended the scope of DTC genetic testing to include tests that are 'commissioned by the consumer but where a medical practitioner or health professional is involved in the provision of the service'.[7] This definition encompasses genetic tests provided under the new model increasingly applied by DTC companies, which requires consumers to contact a healthcare provider for gaining access to the test or the test results.[8]

Even though DTC genetic tests have been promoted by some companies as empowering consumers to make informed healthcare decisions, increasing autonomy and safeguarding the right to genetic information, this new delivery model is also a source of great concern among scholars, policy makers and professional organizations.[9,10] Opponents of DTC genetic testing have raised concerns regarding the uncertain clinical validity and utility of the tests and the often inadequate and misleading information provided along with such services.[11] Furthermore, it

has been claimed that the dubious quality or absence of pre- and post-test genetic counseling and medical supervision outside the hospital setting could have a negative impact on health decisions and may lead to unnecessary visits to medical professionals, overburdening the healthcare system.[10] Additional concerns are raised by the DTC offer of preconception carrier tests including a broad panel of diseases,[12] some of which fail to meet generally accepted criteria of screening programs.[13] This is because such panels may include diseases that are amenable to treatment, mild phenotypes or screen for mutations of limited pathogenicity.[12]

Issues regarding the ethical and legal implications of DTC genetic testing have been widely discussed over the past few years and numerous surveys have been conducted. Most of these studies have taken place in the USA,[14–16] and the main focus of the literature has been on the attitudes of users,[17–19] and, to a lesser extent, those of healthcare providers[20–22] and the general population.[23,24] In contrast, as far as we know, no studies have explored the attitudes of patients and their parents towards DTC genetic carrier testing. Most previous studies addressing their attitudes have assessed their opinions on 'traditional' CF carrier screening programs.[25] Given that DTC preconception carrier testing may significantly influence the reproductive choices of consumers, it is important to examine the moral acceptability of such tests and their potential impact on public health. Therefore, exploring the attitudes of patients with autosomal recessive disorders and their parents may provide valuable insight into this debate on both the normative and the regulatory levels.

The present study was undertaken at the University Hospital Ghent, Belgium, with the aim of investigating the views and attitudes of adult patients (16 years and above) and parents of children with CF regarding preconception carrier screening for autosomal recessive disorders through DTC genetic tests.

Materials & Methods

Research Setting

Parents of children affected by CF and patients aged 16 years and older were asked to complete a questionnaire assessing their attitudes regarding preconception carrier screening for CF.

The study population was recruited from a register of 157 patients with CF who consulted at least once in 3 months at the Department of Pneumology at the University Hospital of Ghent, where one of the eight Belgian reference centers for CF is located. All CF patients aged 16 years and older who attended the clinic in the period from August to December 2012 were invited to participate. In case of patients aged under 16 years, their parents were asked to fill out the questionnaire. An envelope including an information letter, an informed consent form, a questionnaire and a reply envelope was personally handed to the potential participants by the nurse at the clinic. Completed questionnaires were separated from written consents to guarantee anonymity. An approval from the local Institutional Review Board was obtained.

Questionnaire

This research is part of a larger study involving not only the investigation of the attitudes towards DTC testing, but also the attitudes toward preconception carrier screening for cystic fibrosis and related reproductive choices.

A questionnaire comprising a series of closed questions, binary questions, multiple-choice questions and Likert scale questions was developed. The questionnaire was pilot-tested by several specialists, researchers, a CF patient and her parents. Completing the questionnaire took approximately 20 min

In order to ensure understandability of the content to the participants, all key concepts were explained and reader-friendly clarifications were provided within the questionnaire. In addition, carrying out the survey in a clinical setting provided participants with an opportunity to address members of our research team for any further explanations.

The questionnaire was divided into multiple sections. First, sociodemographic characteristics of the participants were assessed, including age, sex, religious beliefs and highest level of education. The following sections addressed study participants' personal experience with CF, attitudes toward carrier screening for CF, previous and intended reproductive behaviors, as well as stance on prenatal diagnosis and termination of pregnancy. The next section assessed the attitudes toward preconception carrier screening for CF. The remainder of the questionnaire

was devoted to exploring awareness of, and attitudes towards DTC genetic testing among study participants. The present paper focuses on this final component of the survey.

Data Analysis

Data were analyzed using SPSS21 for Windows. The 5-point scales were reduced to three categories to avoid empty or small cells. Responses 'fully disagree' and 'disagree' as well as responses 'agree' and 'fully agree' were combined to form 'disagree' and 'agree', respectively. The third category was 'Neither agree nor disagree.' Level of education was also recoded to three categories: 'Primary education', 'Secondary education' and 'Higher education.' Age was divided into three groups: <26 years, 26–35 years and ≥36 years.

Statistical significance was determined using nonparametric tests (Spearman's rank correlation coefficient, Chi-squared test, Fisher's exact test).

Results

The total study population comprised 157 individuals, including both patients and parents. Among these, there were six pairs of siblings under the age of 16 years, whose parents were given only one questionnaire per sibling-pair. Overall, a total of 25 potential participants were excluded. Of the excluded individuals, nine persons (four parents and five CF patients aged 16 years or older) could not be reached within the time frame of the study, six parents of children with CF insufficiently understood the Dutch language, five CF patients aged 16 years and older had intellectual disability and two parents of CF patients had mental retardation. Two CF patients under the age of 16 years were accompanied by their non-biological parents, who were also excluded. A total of 134 questionnaires were distributed of which 112 were returned. Of the 75 questionnaires provided to the parents, 65 were completed (response rate 86.7%). Upon conclusion of the survey, an additional questionnaire was excluded from the analysis because it had been completed incorrectly by the participant. Of the questionnaires distributed to the CF patients aged 16 years and older, 47 (out of 59) were completed (response rate 79.7%). Participant characteristics are given in .

Table 1. Demographic characteristics of the study population.

Participant characteristics	Parents of cystic fibrosis patients (n=64)	Cystic fibrosis patients (n=47)
Sex		
Male	14	26
Female	50	21
Missing	-	-
Age		
<26 years	3	23
26–35 years	19	16
≥36 years	41	8
Missing	1	-
Religion		
Catholic	39	28
Muslim	2	2
Protestants	1	1
Other religion	2	1
No religion	18	15

Missing	2	-
Highest level of education		
Primary school	2	1
Lower secondary education	7	6
High school	23	25
University	32	15
Missing	-	-

Attitudes Towards DTC Genetic Testing

In our study population, 78.3% of the patients with CF and 87.1% of the parents had no preexisting knowledge of the availability of DTC genetic testing for carrier status of genetic diseases through the Internet. Of the total survey population, 59.3% believe that people have the right to self-initiate a request for a DTC genetic test through a commercial company (). Within this group, 57.1% of participants are of the opinion that the results of such a test should not be communicated without counseling by a physician. 23.8% believe one should be able to obtain results without explanations from a medical professional and 19.0% of participants selected 'neither agree nor disagree'. 69.1% of the total study population believe that all doctors have an obligation to answer questions from patients who self-initiated a DTC genetic test through the Internet, 10% disagree and 20.9% neither agree nor disagree.

Table 2. Attitudes of patients and parents of children with cystic fibrosis toward direct-to-consumer genetic testing.

Statement	Parents			Patients		
	Agree	Disagree	Neither agree nor disagree	Agree	Disagree	Neither agree nor disagree
People have the right to request, on their own initiative, a DTC genetic test to determine carrier status through a commercial company	33/62 (53.2%)	15/62 (24.2%)	14/62 (22.6%)	31/46 (67.4%)	8/46 (17.4%)	7/46 (15.2%)
When you order a genetic test to determine carrier status, you should be able to receive the results without counseling from a physician	10/63 (15.9%)	42/63 (67.7%)	11/63 (17.4%)	10/46 (21.7%)	30/46 (65.2%)	6/46 (13.1%)
Parents have the right to test their children for carrier status of all kinds of diseases through DTC genetic testing	23/62 (37.1%)	23/62 (37.1%)	16/62 (25.8%)	21/46 (45.7%)	15/46 (32.6%)	10/46 (21.7%)
A webpage can provide information, in a clear way, about the pros and cons of carrier testing	29/64 (45.3%)	18/64 (28.1%)	17/64 (26.6%)	17/46 (37%)	15/46 (32.6%)	14/46 (30.4%)
A doctor should answer questions from patients who underwent a DTC genetic test on their own initiative	44/64 (68.7%)	6/64 (9.4%)	14/64 (21.9%)	32/46 (69.5%)	5/46 (10.9%)	9/46 (19.6)
The offer of a DTC genetic test for carrier status has more benefits than potential risks	11/64 (17.2%)	19/64 (29.7%)	34/64 (53.1%)	6/45 (13.3%)	17/45 (37.8%)	22/45 (48.9%)
It should be forbidden by law to offer genetic tests for carrier status through a commercial company	27/63 (42.8%)	18/63 (28.6%)	18/63 (28.6%)	18/46 (39.1%)	9/46 (19.6%)	19/46 (41.3%)
It should be forbidden by law to offer DTC genetic tests on the website of a hospital	22/63 (34.9%)	21/63 (33.3%)	20/63 (31.8%)	13/46 (28.3%)	13/46 (28.3%)	20/46 (43.4%)

I would get tested for carrier status of other conditions than cystic fibrosis through the Internet	6/63 (9.5%)	45/63 (71.4%)	12/63 (19.1%)	2/46 (4.3%)	39/46 (84.8%)	5/46 (10.9%)

DTC: Direct-to-consumer.

Among the participants, 40.7% indicated that parents have the right to test their children for carrier status for all kinds of diseases through DTC genetic testing companies.

A correlation was found between participants who feel that one has the right to self-initiate requests for DTC genetic tests to determine carrier status through a commercial company and the right to test their children for all kinds of genetic disorders using such a test (Chi-squared test $p < 0.001$, Spearman's rank correlation coefficient (r_s) = 0.402). The positive value of the Spearman's correlation coefficient indicates that the respondents who support the right to order carrier tests from commercial providers are also likely to favor testing of children for carrier status by their parents.

A total of 41.3% of the participants believe the law should forbid genetic testing to be offered through commercial companies. Within this group, 61.4% think that it should also be prohibited by law to offer genetic tests on a hospital website, 11% believe it should be allowed and 2.73% neither agree nor disagree. By means of the Spearman's correlation coefficient ($r_s = -0.426$) and the Chi-squared test ($p < 0.05$), a correlation was found between both groups. Surprisingly, a significant correlation was found between those who believe that the law should forbid genetic testing to be offered through commercial companies and those who believe that people have the right to initiate requests for DTC genetic tests through a commercial company (X^2, $p < 0.001$, $r_s = -0.354$).

In the entire study population, 7.3% would get tested through the Internet for diseases other than CF, 77.1% would not, and 15.6% did not know.

Finally, we investigated whether participants who would get tested for conditions other than CF within the standard healthcare setting, would also get tested through the Internet ($r_s = 0.115$). As shown in , 53.1% of the parents and 59.1% of the patients would undergo carrier screening for conditions other than CF before pregnancy through standard healthcare channels. Within this group, 18.2% of the parents and 4% of the patients would access a screening test for conditions other than CF through the Internet. 60.6% of the parents and 84% of the patients, who would get tested for conditions other than CF through standard healthcare services, would not opt for a DTC genetic test through the Internet for those conditions. 18.8% of parents and 14.9% of patients would not access testing for other conditions before pregnancy through either standard healthcare, or via the Internet. No difference could be found between the attitudes of the parents and patients.

Table 3. Comparing respondents' attitudes toward direct-to-consumer carrier testing through the regular healthcare and through direct-to-consumer genetic testing companies.

			Question 2‡				
			Agree	**Disagree**	**Neither agree nor disagree**	**Missing**	**Total**
Parents	Question 1†	Agree	6	20	7	1	34
		Disagree	0	12	1	0	13
		Neither agree nor disagree	0	13	4	0	17
		Missing	0	0	0		0
	Total		**6**	**45**	**12**	**1**	**64**
Patients	Question 1	Agree	1	21	3	1	26

		Disagree	0	7	0	0	7
		Neither agree nor disagree	0	9	2	0	11
		Missing	1	2	0		3
	Total		**2**	**39**	**5**	**1**	**47**
Total	Question 1	Agree	7	41	10	2	60
		Disagree	0	19	1	0	20
		Neither agree nor disagree	0	22	6	0	28
		Missing	1	2	0		3
	Total		**8**	**84**	**17**	**2**	**111**

†Question 1: I would get tested before pregnancy for conditions other than cystic fibrosis (through regular healthcare).
†Question 2: I would get tested for carrier status of conditions other than cystic fibrosis through the Internet.

Due to the relatively small sample size, we did not investigate whether demographic factors such as religion, gender, or education influenced participants' attitudes.

Discussion

The principal finding of our study is that many participants, despite being directly affected by an autosomal recessive genetic disorder, were skeptical of DTC genetic carrier testing in general and, in particular, in the out-of-hospital setting. For example, regarding offering DTC genetic tests through the Internet, a substantial number of participants believe this practice should be prohibited by law. Furthermore, only 17.2% of parents and 13.3% of patients believed that the benefits of a DTC genetic test for carrier status outweigh the potential risks. Such negative attitudes can partly be attributed to the limited awareness of DTC genetic testing among the study participants. Although efforts were made to elucidate key aspects of DTC genetic testing within the questionnaire and all participants had an opportunity to address our research team for additional explanations, the novelty of the concept to some participants may have nevertheless contributed to the overall negative perception of DTC genetic testing. Low awareness of DTC genetic testing has also been reported previously by several other studies. For instance, in a US-based survey conducted in 2008 by Kolor *et al.*,[26] the level of awareness for personal genome testing only reached 22%, while in a study performed in the UK in the same year, just 13% of the studied population was familiar with such tests.[27]

Our study also found that both parents and patients would prefer to undergo a carrier screening test in the healthcare setting rather than receiving testing through DTC genetic testing companies. Only a small minority of participants (9.5% of parents and 4.3% of patients) would choose to purchase a carrier screening test from commercial providers through the Internet. Contrary to this, the majority (53.1% of the parents and 59.1% of the patients) indicated that should similar tests be provided through standard healthcare channels, they would opt for the test. Arguably, the greater willingness to access the test through healthcare among study participants can largely be explained by CF patients' and parents' familiarity with, and trust in healthcare services. Individuals' preferences between healthcare and commercial companies as providers of genetic testing have not been explored sufficiently in the literature. In this paper we report preferences among CF patients and parents who had limited awareness of commercial DTC genetic testing and extensive personal experience with healthcare services. It would be desirable if future studies explored similar preferences among other stakeholders such as, for example, individuals who have taken a commercial DTC genetic test.

Interestingly, most patients and parents in our study population indicated that individuals have the right to request a genetic test through a DTC genetic testing company, even when they were of the opinion that DTC genetic tests

should be prohibited by law. Although appearing contradictory, these responses may illustrate two important sentiments among the study participants. The first is the belief that people have a right to access their genetic information, including their carrier status for recessive disorders. Information pertaining to one's genetic make-up can be viewed as something highly personal for many people and they may consider it important to have access to this kind of information upon request.[28] The second sentiment reflects the lack of trust in DTC genetic testing companies coupled with generally negative attitudes towards DTC genetic tests for carrier status, as previously discussed. Regarding the apparent contradiction between the two responses, it is likely that some of the participants were in favor of prohibiting DTC genetic testing in its current form (i.e., through the Internet and without adequate involvement of medical professionals), but were not against the practice in principle.

Despite the fact that the majority of participants perceived consumers to have the right to directly access genetic tests, 57.1% of those who agreed with this statement also believed that genetic counseling should always accompany the communication of tests results. The high importance our participants attach to the traditional physician-centered model is not surprising, taking into account that as patients, or parents of patients, they are rather familiar with this system and seem to value it highly. Placing increased importance on genetic counseling does not seem to be a characteristic of only patients and their families. Our finding is in line with evidence presented by numerous surveys conducted in healthy potential consumers of DTC genetic tests, in whom most would feel the need to share the test results with a healthcare professional.[27,29] In addition, a survey by Brett *et al*.[30] regarding the experience of healthcare professionals with DTC genetic testing, also supports these findings, by reporting that 80% of patients having undertaken DTC genetic testing consulted a physician on their test results.

The consumers' desire for medical professionals to provide consultation on their results seems to be supported by the view that healthcare professionals actually have an obligation to counsel patients when it comes to DTC genetic testing. A large majority (69.1%) of the participants in our study were of the opinion that every doctor should be willing to provide medical advice to patients who have taken the initiative to use DTC genetic tests. Similar findings were presented in the study by McGuire *et al*.,[23] where 61% of the participants also stated that consulting patients on genetic test results constitutes a professional obligation for physicians. On the other side of the spectrum, several surveys indicate that healthcare professionals seem to also consider it to be their professional obligation to provide counseling regarding test results.[20,22] However, an important caveat regarding counseling on genetic tests by physicians is that not all medical professionals may be sufficiently informed about DTC genetic testing and thus they might not be in a position to provide high-quality counseling to the patients. Better physician education is necessary to ensure that the patients receive adequate information on their test results.

Regarding DTC genetic testing in children, 40% of the participants agreed that parents have the right to test their children for carrier status. This finding might indicate that parents perceive testing their children for carrier status as an expression of their right to make healthcare decisions for their children, as well as an assertion of the right to access DTC genetic testing and genetic information. In this regard, a correlation was found between those who felt that undergoing DTC genetic testing is a right and those who agreed that it is a parental right to have their children tested through such tests. Similar findings were reported in the study by McGuire *et al*.,[23] where 63% of the participants believed that parents should be able to test their children through DTC genetic tests.

Nevertheless, the participants' belief that testing children falls within the scope of their parental rights, clashes with several professional guidelines and recommendations on pediatric genetic testing. As observed in a systematic review of guidelines and position papers regarding carrier testing in minors, by Borry *et al*.,[31] all guidelines reviewed discourage children from undergoing carrier testing. This critical approach towards undergoing genetic testing for carrier status during childhood is based on the possible violation of some of the minor's most fundamental rights in this context. As underlined by the British Society of Human Genetics, carrier tests with predominantly reproductive implications, if taken prematurely and without compelling reasons, might deprive children of their right to make autonomous healthcare decisions in the future.[32] Furthermore, informed consent cannot be ensured if the person tested does not have a complete understanding of the risks and benefits of the tests, which should be performed voluntarily and without any form of external pressure. In addition, given the sensitive nature of information revealed by such tests, a carrier status test performed in childhood might infringe the child's right to confidentiality and privacy, as well as the right not to know.[31]

Limitations

Although there are eight reference centers in Belgium for patients with CF, participants for the present study were recruited from a single CF patient register at one university hospital. Limiting the scope of the study to a single medical center increased the ease with which preparation and administration of the survey could be conducted without significantly compromising the sample size. On the other hand, focusing on a single center may have resulted in a geographically uniform sample with few participants coming from other parts of Belgium. The findings of the present study, therefore, cannot be readily generalized to a larger population.

A great majority of the study participants (78.3% of the patients with CF and 87.1% of the parents) had never heard of DTC genetic testing for carrier status through a commercial provider. Although efforts were made to elucidate all relevant concepts within the questionnaire, the novelty of the practice to most participants may have been partly responsible for the generally negative attitudes toward DTC genetic testing.

Finally, it is likely that the attitudes of CF patients and parents towards carrier screening for autosomal recessive conditions may be largely shaped by personal experience with the disease, such as individual medical history, perception of the disease severity, and prognosis. We believe it would be valuable to explore influence of such personal factors through a qualitative study, such as in-depth interviews. This, however, was not feasible within the scope of the present study.

Conclusion

Our study has revealed a low prior awareness of DTC genetic testing for carrier status among patients and parents of children with CF. Although study participants believed that people should have a right to access DTC genetic testing through commercial companies, only a small minority would themselves purchase a carrier test sold on the internet. However, majority of participants were willing to accept a similar test if offered by the regular healthcare services. This finding indicates that while the patients and parents of children with CF may be skeptical of the practice of *commercial* genetic testing, their views towards genetic testing for carrier status are largely positive.

Future Perspective

Traditionally, carrier screening panels have focused on screening for a limited number of conditions. Recently, some direct-to-consumer genetic testing companies have started advertising expanded carrier screening panels aimed at screening for multiple recessive conditions in a single test. We believe that in the near future the number of conditions on screening panels will continue to grow. Furthermore, as the cost of gene sequencing further declines while the technical performance of the tests consistently improves, it is likely that in the near future genome/exome sequencing will be employed as a primary tool for carrier screening.

As the screening technologies become increasingly advanced, important ethical questions will rise as to selecting recessive disorders for screening. For example, inclusion of milder forms of a disease, treatable disorders, or rare and insufficiently understood conditions may prove particularly challenging. Moreover, improving technology to accurately predict a phenotype in offspring may potentially result in a heated societal debate over eugenics and desirability of having children without any health problems. These concerns will further be fueled by prospective parents' wish to avoid birth of affected children, leading to a wider adoption of population carrier screening programs.

Based on the current experience, it is likely that DTC genetic testing companies will continue providing carrier testing services for progressively many recessive conditions in the out-of-hospital setting. Adequate provision of information and counseling in order to allow autonomous reproductive decision-making will become even more challenging. In the light of these concerns, it is important that more attitudinal studies are carried out to assess views of different stakeholders on DTC genetic testing.

In addition, we hope that the healthcare services keep up with the technological developments and start offering carrier screening tests for a select number of recessive disorders. However, this will require successful integration of genetics services into clinical care as well as education of physicians and other healthcare providers on genetic

testing.

Finally, despite improving treatments for CF, we expect that the condition will continue to present significant problems to the affected individual's health. Because of this, it is probable that carrier screening for CF will become more widely acceptable and CF will be included on most carrier screening tests in the next 5–10 years.

Sidebar

Executive Summary

- We have assessed the attitudes of adult patients and parents of children with cystic fibrosis (CF) towards direct-to-consumer (DTC) genetic testing that aim at identifying carriers of autosomal recessive disorders.
- Study population comprised 134 individuals (both parents and adult patients) selected from a CF patient registry in Belgium.
- Prior to participating in our survey, less than 20% of patients and parents were aware of the fact that commercial companies offer DTC carrier screening tests through the Internet.
- Fifty-nine percent of study participants believe people should have a right to access DTC genetic tests provided by commercial companies.
- However, personal attitudes toward DTC genetic testing were negative. Less than 10% of the participants would themselves choose to take a carrier tests for conditions other than CF through a commercial company.
- Willingness to undergo carrier screening test for recessive conditions was considerably higher (54%) among study participants, should such a test be offered though the regular healthcare services.

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Ethical conduct of research
The authors state that they have obtained appropriate institutional review board approval or have followed the principles outlined in the Declaration of Helsinki for all human or animal experimental investigations. In addition, for investigations involving human subjects, informed consent has been obtained from the participants involved.

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